Before the
Federal Communications Commission
Washington, D.C. 20554

In the Matter of	)
	)
TRANSOMA MEDICAL, INC.	)
	)
Request for Interpretation of Medical Implant Communications Service Rules	)

ORDER

Adopted: February 21, 2007 **Released: February 22, 2007**

By the Deputy Chief, Mobility Division, Wireless Telecommunications Bureau:

1. *Introduction*. We have before us a request[1] from Transoma Medical, Inc. (Transoma), for declaratory ruling (Petition).[2] Specifically, Transoma requests confirmation of its understanding that the rules governing the Medical Implant Communications Service (MICS)[3] permit the use of MICS systems for drug testing by the pharmaceutical industry. We deny the Petition for reasons discussed below.

2. *Background*. The Commission adopted rules establishing the MICS in 1999.[4] The MICS was created in the 402-405 MHz frequency band as "an ultra-low power, unlicensed, mobile radio service for transmitting data in support of the diagnostic and/or therapeutic functions associated with implanted medical devices."[5] It was intended to accommodate "potential life-saving medical technology" while protecting other users of this spectrum from interference.[6] Accordingly, Section 95.1209(a) of the Commission's Rules provides that, "[e]xcept for the purposes of testing and for demonstrations to health care professionals, medical implant programmer/control transmitters may transmit only operational, diagnostic and therapeutic information associated with a medical implant device that has been implanted by a duly authorized health care professional."[7]

3. Transoma seeks confirmation of its understanding that MICS may be used "in medically related industries by the pharmaceutical industry for drug safety and efficacy monitoring and in research related to developing new therapies and physiological understanding of those therapies" for "monitoring physiological parameters of the being that is chosen as the subject of the experiment."[8] It argues that the use of MICS devices in such experiments is consistent with the goal underlying the establishment of the

[1] Letter dated March 13, 2006, from Perry Mills, Vice President and Chief Technology Officer, Transoma Medical, Inc., to Catherine W. Seidel, Acting Chief, Wireless Telecommunications Bureau (Petition).

[2] *See* 47 C.F.R. § 1.2.

[3] *See* 47 C.F.R. §§ 95.1201-95.1219.

[4] *See* Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band, *Report and Order*, WT Docket No. 99-66, 14 FCC Rcd 21040 (1999), *corrected by Errata*, 15 FCC Rcd 12387 (2000) (*MICS Report and Order*).

[5] *Id*. at 21040 ¶ 1.

[6] *Id*.

[7] 47 C.F.R. § 95.1209(a).

[8] *See* Petition at 1. We understand Transoma to be requesting confirmation that the MICS devices can be used for drug testing on animals as well as human beings.

MICS, to enhance the health and quality of life of medical patients, because the devices would be used to develop "new pharmaceuticals and therapies that may ultimately be used by physicians everywhere."[9] Transoma states that it envisions developing products that are fully compliant with the MICS technical requirements, including the capability of using listen-before-talk and adaptive frequency agility techniques to avoid causing or receiving interference from other users of the 402-405 MHz band.[10]

4. *Discussion*. We deny the Petition. The MICS rules clearly contemplate that MICS devices will be used solely for the medical treatment of individual patients by licensed health care providers. The MICS is expressly restricted to use in support of "diagnostic" and "therapeutic" functions.[11] The terms "diagnostic" and "therapeutic" clearly refer in this context to a physician's or other licensed health care provider's use of MICS transmitters to diagnose, monitor and treat conditions of individual patients. Throughout the rulemaking proceeding establishing the MICS, moreover, the service was repeatedly described as one intended to enhance the medical treatment of individual patients.[12] In addition, we note that the rules expressly refer only to implantation of MICS devices in humans.[13] Had the Commission intended to authorize other uses of MICS devices, such as to facilitate

[9] *See id*. Transoma also states that the use of its MICS units in drug experiments "would typically be under the direction and control of duly authorized medical professionals." *Id*.

[10] *Id*. Implanted MICS devices may transmit in two circumstances. First, implanted MICS devices may transmit in response to a transmission from an external medical implant programmer/control transmitter or a non-radio frequency actuation signal generated by an external device. *See* 47 C.F.R. § 95.1209(b). The external medical implant programmer/control transmitter must follow a listen-before-talk protocol before transmitting to ensure that a selected channel is not already occupied. *See* 47 C.F.R. § 95.628. The second circumstance in which an implanted MICS device may transmit is in response to a "medical implant event." *See* 47 C.F.R. § 95.1209(b). A medical implant event is "[a]n occurrence or the lack of an occurrence recognized by a medical implant device, or a duly authorized health care professional, that requires the transmission of data from a medical implant transmitter in order to protect the safety or well-being of the person in whom the medical implant transmitter has been implanted." *See* 47 C.F.R. Part 95, Subpart E, Appendix 1 - Glossary of Terms.

[11] *See MICS Report and Order*, 14 FCC Rcd at 21040 ¶ 1; 47 C.F.R. § 95.1209(a). Although Section 95.1209(a) also refers to the transmission of "operational" information as well as "diagnostic and therapeutic" information, this additional modifier cannot be read as authorizing the use of MICS in drug testing, but rather as reflecting that the rule authorizes operation of MICS devices in demonstrations to health care professionals and for testing the operation of the devices.

[12] *See, e.g*., Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band, *Notice of Proposed Rule Making*, WT Docket No. 99-66, 14 FCC Rcd 3659, 3661 ¶ 6 (1999) (noting that the Commission "anticipate[s] that medical implant devices developed under the MICS would provide a safer, less expensive, and less invasive method to diagnose and manage *patient* conditions than the inductive systems now used") (footnote omitted, emphasis added); *id*. at 3663-64 ¶ 10 (noting that an allocation of ten channels of 300 kilohertz each for MICS will, *inter alia*, "allow the system to avoid interference from other radio frequency devices that are used in *clinical environments*, and will help to protect *patients* from any jamming or data corruption occurring as a result of another device being within range of the implant") (emphases added); *MICS Report and Order*, 14 FCC Rcd at 21042 ¶ 4 (noting, with tacit agreement, a commenter's assertion that "the MICS would permit physicians and their patients to take advantage of the benefits of wireless technology to improve the medical care and capabilities of implanted medical devices, *thereby improving these patients' quality of life*") (emphasis added); *id*. at 21042 ¶ 5 (noting, with tacit agreement, other commenters' statements that MICS would serve the public interest by enhancing patient care and treatment).

[13] *See* 47 C.F.R. Part 95, Subpart E, Appendix 1 - Glossary of Terms (defining "medical implant event" as an occurrence that requires the transmission of data "in order to protect the safety or well-being of the *person* in whom the medical implant transmitter has been implanted," "medical implant transmitter" as "[a] MICS transmitter that operates or is designed to operate within a *human body* for the purpose of facilitating communications from a medical implant device," and "medical implant device" as an "[a]pparatus that is placed inside the *human body* for the purpose of performing diagnostic or therapeutic functions") (emphases added). We note that the Commission

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research and development by the pharmaceutical industry, we believe it would have done so expressly.[14]

5. Transoma acknowledges that research and development applications could be outside the scope of the MICS rules "because the discussions surrounding MICS during the development of the rulemaking focused primarily on implants placed in patients for the purpose of improving their health and quality of life."[15] Transoma argues, however, that the proposed use of MICS devices in pharmaceutical studies could lead to the development of new therapies that "may have as great or even greater impact on the health and quality of life for a much larger patient base than usage in the classical sense of an implanted patient and as such these application should fall within the scope of the MICS rules."[16] We disagree. The public interest benefits of extending the use of the MICS to medical research and development efforts is a matter that is properly considered in the rulemaking context, where those benefits can be weighed against other factors, such as the interference impact of such expanded use. Whatever the merits of such an expansion as a matter of policy (on which we express no view herein), it provides no basis for interpreting the MICS rules in a manner contrary to their plain language and the Commission's plain intent in adopting the rules.

6. *Conclusion*. We conclude that the Commission's rules authorize the use of MICS devices only for the diagnosis, monitoring and treatment of human patients, and that MICS devices may not be used in pharmaceutical research and development activities, such as testing the safety and efficacy of new drug protocols, that do not involve the treatment of patients. We accordingly deny the Petition.

7. Accordingly, IT IS ORDERED, pursuant to Section 4(i) of the Communications Act of 1934, as amended, 47 U.S.C. § 154(i), and Section 1.2 of the Commission's Rules, 47 C.F.R. § 1.2, that the request for declaratory ruling filed by Transoma Medical, Inc. on March 13, 2006, IS DENIED.

8. This action is taken under delegated authority pursuant to Sections 0.131 and 0.331 of the Commission's Rules, 47 C.F.R. §§ 0.131, 0.331.

FEDERAL COMMUNICATIONS COMMISSION

Scot Stone
Deputy Chief, Mobility Division
Wireless Telecommunications Bureau

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selected the 402-405 MHz band for MICS operations due in part to its signal propagation characteristics in the human body. *See MICS Report and Order*, 14 FCC Rcd at 21042-43 ¶ 6.

[14] *See also* Investigation of the Spectrum Requirements for Advanced Medical Technologies, *Notice of Proposed Rulemaking, Notice of Inquiry, and Order*, ET Docket No. 06-135, 21 FCC Rcd 8164, 8165 ¶ 1 (2006) ("In this proceeding, the Commission intends to modify its rules to accommodate the development and use of a variety of new medical devices that rely on radiocommunication for critical aspects of their functionality. . . . For health care providers and patients, such wireless implant monitoring technologies have the potential to lower medical costs by extending the time between hospital visits and surgical procedures."); *id.* at 8167 ¶ 7 ("The MICS service was anticipated to transmit data in support of the diagnostic and/or therapeutic functions associated with implanted medical devices to enable individuals and medical practitioners to utilize potential life-saving medical technology without causing interference to other users of the spectrum.").

[15] *See* Petition at 1.

[16] *Id*.